

**Specification**

The patent acknowledges the prior EPA scientific claim that as arsenic-in-drinking-water levels are reduced from high levels, at and above 1,000  $\mu\text{g/L}$  (parts per billion [ppb]), towards zero (0)  $\mu\text{g/L}$  bladder cancer mortality rates will monotonically – actually, strictly monotonically -- decrease. The patent acknowledges the general soundness of the EPA claim from about 1000  $\mu\text{g/L}$  to 50  $\mu\text{g/L}$ , not only for bladder cancers but for broader groupings of cancers and other health effects. However, the heart of the Kayajanian's patent claim is that for certain specified cancers, certain cancer groupings and total cancers, the cancer incidence and mortality rates significantly INCREASE as the arsenic level in drinking water decreases from around 50  $\mu\text{g/L}$  to immeasurable levels or 0  $\mu\text{g/L}$ . No patent claim is made that arsenic levels should be lowered to around 50  $\mu\text{g/L}$  from higher levels -- a desirable public health goal, obvious on its face. That claim has already been made by the EPA. The patent claim is arsenic levels in drinking water below the range 25  $\mu\text{g/L}$  should be increased by the addition of arsenic to reach 25  $\mu\text{g/L}$  but not exceed 75  $\mu\text{g/L}$ . This addition of arsenic could be made at any point in the water distribution process, though the addition of arsenic is more feasible further in the distribution pipeline from the water drinker than nearer. Logically, if the arsenic level is between 25 to less than 75  $\mu\text{g/L}$ , it should be maintained at that level. The terms "increase" and "maintain" refer, respectively and obviously, to 0 to less than 25  $\mu\text{g/L}$  and 25 to less than 75  $\mu\text{g/L}$ . The invention would apply world-wide though obviously not in those water systems where arsenic levels are 75  $\mu\text{g/L}$  and higher.

How could this invention be practiced in the United States in the face of an EPA regulation that set an upper limit of 10  $\mu\text{g/L}$  arsenic in drinking water? That regulation applies only to community water systems, not to all water systems and not to individual wells. Further, individuals deriving water from community water systems could add arsenic to their own water. Further, regulations, like the one creating a 10  $\mu\text{g/L}$  arsenic standard, can be set aside by Federal Courts, superceded by law or their application to community water systems can be blocked by Federal Court order. The fact that current EPA regulations make difficult or diminish the applicability of the invention does not diminish its inherent value or worth. In a perverse sense, the EPA movement from a 50  $\mu\text{g/L}$  regulatory standard to 10  $\mu\text{g/L}$  serves as a testament to the novelty of the invention.